Exhibit 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DECLARATION OF PAMELA DOWNS

Pamela Downs declares and says:

1. My name is Pamela Downs. I am over twenty-one years of age and of sound mind. I am competent to affirm all of the matters set out in this Declaration.

2. I am employed as a Senior Director at Epiq Systems, Inc., eDiscovery and Litigation Solutions. During my 26 year career supporting the legal services industry, I have developed extensive experience in the assessment, collection and production of hard copy and electronically stored information in litigated matters.

3. Following my previous Declaration to this Court on behalf of Ethicon, I was asked to further investigate the specific scope of Regulatory Affairs documents maintained by Ethicon in the regulated markets outside the United States ("ex-US"), along with the burdens that would be associated with the potential collection of those documents. I determined that the 15 mesh products that I understand are at issue in this litigation are regulated in approximately 67 countries ex-US. During the course of my investigation, I interviewed Regulatory Affairs employees representing 46 of the ex-US regulated markets. I determined that the US and EU Regulatory Filings that have been or are being produced are relied upon for all Regulatory Submissions or Registrations in those countries. Accordingly, as explained further below, a global collection of ex-US Regulatory documents would be largely duplicative of prior or ongoing productions and would involve a substantial burden. The total costs, including those associated with interviews of and/or collections from an additional approximately 150 ex-US

employees, processing and translation of 150,000 to 250,000 estimated pages, would range from an estimated $500,000 to $1,000,000.

4. For the pelvic mesh products sold in countries outside of the US, the Country Specific Regulatory Affairs Submissions and related documents are generally stored in the country of registration and are not aggregated in a central repository.

5. The US and EU Regulatory Affairs Records, Design Dossiers, Technical Files and similar Regulatory Affairs documents relied on by ex-US countries for in-country Submissions are aggregated in official Regulatory Affairs SharePoint Sites and network file shares.

6. The primary ex-US Regulatory Affairs document/file types are i) In-Country Regulatory Submissions or Registrations, Renewals and supporting documents; ii) Reportable Adverse Event and Field Event Reports to In-Country Authorities; and iii) Country-specific Labels regulated by In-Country Authorities.[1]

7. A few countries (Belarus, China, Japan, Russia, Sri Lanka, and the Ukraine) have other substantively unique Regulatory requirements such as independent or government approved in-country laboratory or clinical testing.

8. The US Certificate for Foreign Government, the EU Certificate for Free Sale or the European CE Mark and their supporting documents that I understand have been or are being collected, reviewed and produced are relied upon for all In-Country Regulatory Submissions or Registrations and Renewals. In some countries, these documents must be translated but they are literal translations of the US or EU Regulatory documents utilized to complete the In-Country Regulatory Submission or Registration process thereby creating a slightly unique document maintained in-country.

9. The previously produced Design Dossiers and Technical Files are relied upon for In-Country Regulatory Submissions or Registrations and Renewals. They are duplicates or translations of the official Design Dossier and Technical File Records.

[1] I have also determined that based on local regulations, various countries may also maintain additional miscellaneous document types, such as i) Price Declarations; ii) Sales Declarations; iii) Licenses required for in-country Sales Representatives; iv) local Company, Importer and Distributor information; v) Manufacturing information; and vi) Endorsed Instructions for Use.

10. The Adverse Event and Field Report information reported to In-Country Authorities is supported or prepared by Global Customer Quality, thus, creating a unique local record of the previously produced Global Adverse Event information and the Global Product Quality Issue and Field Report information that I understand have been or are being collected, reviewed and produced.

11. The In-Country Label and Multi-lingual Instructions for Use originate from the previously produced Ethicon US Global Label content management system. The In-Country Label is a translated or only slightly modified (e.g. to include the local company information, local approval information or local language) version of the previously produced Global Label.

12. A global collection of ex-US Regulatory Affairs documents in the 67 regulated countries will be a substantial undertaking, costing $500,000 to $1,000,000. Ethicon's outside counsel, consultants, and in-country employees will need to coordinate efforts, identify the relevant duplicative, translated or slightly modified documents (paper and electronic form), collect the information at the direction of Counsel, and send the information to the United States for translation back to the language of origin, review and production.[2]

i) This undertaking will require new and supplemental interviews with approximately 150 employees.

ii) Based on the previous collections of in-country Regulatory documents and my fact finding, this global collection will likely produce 150,000 to 250,000 pages of country specific forms, duplicative or translated US and EU Regulatory Submission materials, duplicative or translated Design Dossiers, duplicative Instructions for Use, and translated Global Labels.

iii) The estimated cost to collect, process, translate, host, review and produce this information is approximately $500,000-$1,000,000, based on the previous collections of in-country Regulatory documents in Australia, France and Japan and the French and Japanese translations. (There are likely to be languages and file types in the 67 country population that are not machine translatable and will therefore require human translation, which is more expensive.)

[2] It is my understanding that some EMEA countries within the 67 regulated countries only require the CE Mark Classification and Marking. I anticipate that such countries will have more limited collections as Ethicon maintains that information regionally and it is supplied upon request to a Regulatory Authority.

13. It is my understanding that Ethicon has previously produced many of the ex-US regulatory related documents including responsive documents from the following sources:

i) Global Regulatory Dossier Management SharePoint. Used by International Regulatory Group to provide supporting documents about products used by ex-US regulatory affiliates for regulatory submissions.

ii) Regulatory Affairs/TF DD/INC SharePoint. Location for archiving Technical Files and Design Dossiers commonly needed for filings with regulatory authorities.

iii) Regulatory Affairs/RA-CAPA/EWHU Draft TFDD SharePoint. Location for the most recent Technical Files and Design Dossiers needed for filings with regulatory authorities.

iv) Somerville Regulatory Affairs Departmental Share/RA TECHNICAL FILES & DESIGN DOSSIERS DATABASE folder. Contains product technical and design files for ex-US regulatory affiliates for regulatory submissions.

v) Somerville Regulatory Affairs Departmental Share/RA submissions Dutch Health Care Inspection subfolder.

vi) Somerville Regulatory Affairs Departmental Share/RA submissions to MHRA subfolder.

vii) Ex-US Regulatory files to the extent they have been included in any custodial collection in the pelvic mesh litigation and are responsive.

viii) Regulatory documents from Japan, France and Australia at the specific request of plaintiffs counsel (with respect to Japan and France, this required extensive and costly translations).

ix) Global Labeling Content Management System (Agile) including Global Labels and IFU's.

x) The Global Adverse Events for the products at issue.

xi) Product Quality Issue Reports and Recall documents for certain products at issue (earlier in the litigation when I understand the product scope was smaller).

14) It is my understanding that Ethicon is currently in the process of collecting, reviewing and producing additional ex-US regulatory related documents including:

i) Additional documents from the Global Regulatory Dossier Management SharePoint. Used by International Regulatory Group to provide supporting documents about products used by ex-US regulatory affiliates for regulatory submissions.

ii) Regulatory Affairs/International Regulatory SharePoint – This is a portion of the U.S. Regulatory Affairs SharePoint includes Certificates of Free Sale and Certificates to Foreign Government.

iii) Product Quality Issue and Field Action SharePoint sites and additional hardcopy files. These SharePoint sites and files include documents related to Product Quality Issues and Recalls.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 2nd day of August, 2013.

Pamela Downs

PAMELA DOWNS